DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0362]

‘‘Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients;’’ Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ‘‘Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients,’’ dated December 2002. The guidance document provides guidance on quarantine of blood and blood products previously collected from such donors. Because of the likelihood of vaccination of many people with smallpox, these measures are intended to reduce the possibility of vaccinia virus transmission by blood and blood products.

DATES: Submit written or electronic comments on agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one

self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Michael D. Anderson, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients,'' dated December 2002. The guidance document provides information that would help in instances related to the possible risk of vaccinia virus transmission by blood or blood products. Although the presence of vaccinia virus in blood has rarely been documented, this possibility has not been assessed using laboratory techniques. Therefore, the risk of vaccinia transmission by blood and blood products is uncertain. In addition, unlike many vaccines, the smallpox vaccine causes a scab, which can contain infectious vaccinia virus. It is prudent, therefore, to temporarily defer donors

for an appropriate period of time. This guidance applies to collections of Whole Blood, blood components (including recovered plasma), Source Leukocytes, and Source Plasma intended for use in transfusion or for further manufacturing into injectable products. FDA developed the recommendations in this guidance in consultation with experts on vaccinia virus at the Centers for Disease Control and at the Department of Defense. This document is intended to provide guidance pertaining to pre-event, nonemergency, smallpox vaccination. In the event of widespread emergency vaccination due to an actual or impending smallpox outbreak, the risk-benefit situation may differ significantly, and these recommendations for donor deferrals, and for product quarantine and retrieval may need to be modified according to the circumstances and available scientific information.

This guidance is being issued in accordance with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance immediately because the agency has determined that prior public participation is not feasible or appropriate. FDA made this determination because vaccination programs may start soon, and blood establishments need to clarify the suitability of donors who have been recently vaccinated or who have been infected through close contact with a recently vaccinated person. Interested persons may submit to the Dockets Management Branch (see

ADDRESSES) written or electronic comments regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/ohrms/dockets/default.htm or www.fda.gov/cber/guidelines.htm.

Dated: August 13, 2002.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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